IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

R.J. REYNOLDS TOBACCO COMPANY; SANTA FE NATURAL TOBACCO COMPANY, INC.; ITG BRANDS, LLC; LIGGETT GROUP LLC; NEOCOM, INC.; RANGILA ENTERPRISES INC.; RANGILA LLC; SAHIL ISMAIL, INC.; and IS LIKE YOU INC.; *Plaintiffs*, *v.* UNITED STATES FOOD AND DRUG ADMINISTRATION; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT CALIFF, in his official capacity as Commissioner of the United States Food and Drug Administration; and XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services; *Defendants.*	CIVIL ACTION NO. 6:20-cv-00176

PLAINTIFFS' MOTION TO POSTPONE THE RULE'S EFFECTIVE DATE

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INTRODUCTION

FDA's Rule requires massive graphic warnings on the top 50% of the front and back of every cigarette package and 20% of every cigarette advertisement—an unprecedented mandate. One would expect FDA to have compelling evidence and rigorous analysis to justify this extraordinary intrusion. Yet FDA's rulemaking process reveals the opposite: its own studies undermine rather than support the Rule, it ignored obvious less-burdensome alternatives, it concealed key data and limited public input, and it exceeded its statutory authority. Absent immediate relief from this Court, Plaintiffs will imminently face irreparable harm—including tens of millions of dollars in unrecoverable costs and thousands of employee hours—from preparing to comply with this unlawful mandate.

In this lawsuit, Plaintiffs have argued that the warnings are unlawful on First Amendment grounds and on statutory grounds. This Court held that the Rule violated the First Amendment, and thus did not reach the question whether the Rule violates the APA or the Tobacco Control Act (TCA). The Fifth Circuit reversed as to the First Amendment claim and remanded to this Court to address the "complicated" and "fact-intensive" statutory claims. *R J Reynolds Tobacco Co. v. FDA*, 96 F.4th 863, 887 (5th Cir. 2024). Importantly, in addressing the First Amendment claims, the Fifth Circuit did not consider whether the record evidence adequately supports the Rule, and thus its First Amendment ruling in no way controls the statutory issues now before this Court.

Plaintiffs now seek a stay postponing the Rule's effective date while the Court considers their statutory claims. Each stay factor compels that result. First, Plaintiffs are likely to succeed on the merits. FDA violated the APA in multiple ways—most notably, by promulgating a Rule that the record evidence shows would not advance FDA's goal of educating the public about specific smoking risks and instead would mislead and confuse consumers. FDA also violated the APA by ignoring alternatives, conducting a cost-benefit analysis that did not quantify the Rule's benefits, ignoring peer reviewers' fundamental criticisms, withholding necessary information from the public, and giving the public just fifteen days to comment on FDA's qualitative studies. The Rule also contravenes the TCA by increasing the total number of warnings and replacing some of the Act's textual warnings.

As this Court has repeatedly concluded, the balance of the equities favors Plaintiffs. *See, e.g.*,

Doc. 33, 80, 89, 91, 92, 93, 94. The reasoning supporting the Court's previous orders applies here. Plaintiffs will face enormous irreparable harm during the litigation, including "imminent compliance costs" of tens of millions of dollars and thousands of employee hours, which, as this Court has recognized, "would not be reimbursed by the government if plaintiffs prevail on the merits," and thus constitute irreparable harm. Doc. 33 at 1-2.[1] And the public would face no countervailing harm from postponement—as shown by, among other things, FDA's lack of urgency in issuing the Rule and litigating this case.

Pursuant to 5 U.S.C. § 705, Plaintiffs seek a postponement of the Rule's effective date while their statutory claims proceed.[2] In addition, Plaintiffs seek an administrative stay in order to preserve the status quo while the Court considers Plaintiffs' postponement motion.[3]

STATEMENT OF THE CASE

A. FDA Issues the Graphic-Warnings Rule.

The TCA requires that cigarette packages and advertising eventually bear one of nine textual warnings. 15 U.S.C. § 1333(a)(1), (b)(1). It also requires FDA to "issue regulations that require color graphics depicting the negative health consequences of smoking to accompany" these warnings. *Id.* § 1333(d)[1]. The TCA specified that these graphic and textual warnings (and related labeling requirements) would have a single implementation date of fifteen months after issuance of valid regulations implementing graphic warnings. *See* Pub. L. No. 111-31, §§ 103(q)(5), 201(b), 301 (2009). Together, the textual warnings and graphics occupy the top 50% of the front and back of cigarette

[1] Citations to an ECF document ("Doc.") are to the page number added by ECF.

[2] Per Local Rule CV-7(g), Plaintiffs respectfully request an oral hearing on their postponement motion.

[3] *See, e.g.*, *Texas v. United States*, No. 6:24-cv-00306-JCB, ECF No. 27 at 3 (E.D. Tex. Aug. 26, 2024) (issuing administrative stay based on "first-blush review"); *id.*, ECF 54 at 1-2 (E.D. Tex. Sept. 4, 2024) (courts can enter "temporary, injunctive relief based significantly on case-administration needs," "as a flexible, short-term tool" to preserve the status quo); *Tex. Democratic Party v. Abbott*, 961 F.3d 389, 396 (5th Cir. 2020) (granting "temporary administrative stay"). To conserve judicial resources, a court may grant an administrative stay and then permit plaintiffs to "supplement and replace" their postponement motion "with additional briefing … pertinent to summary judgment." *See Texas v. United States*, ECF No. 27 at 8 (Aug. 26, 2024).

packages and 20% of cigarette advertising. 15 U.S.C. § 1333(a)(2), (b)(2).

In 2011, FDA issued a rule requiring that all cigarette packages and advertising bear one of nine disturbing images, including a body with a massive incision, diseased body parts, and a wailing baby. 76 Fed. Reg. 36,628 (June 22, 2011) ("2011 Rule"). The 2011 Rule was invalidated under the First Amendment. *See R.J. Reynolds Tobacco Co. v. FDA*, 845 F. Supp. 2d 266 (D.D.C. 2012), *aff'd*, 696 F.3d 1205 (D.C. Cir. 2012), *overruled in part by Am. Meat Inst. v. USDA*, 760 F.3d 18 (D.C. Cir. 2014) (en banc).

In 2019, FDA again issued a proposed graphic-warnings rule. 84 Fed. Reg. 42,754 (Aug. 16, 2019) ("Proposed Rule"). FDA received extensive comments. *See, e.g.*, Doc. 1-4, 1-5, 1-6, 1-7. In March 2020, FDA issued the final Rule. 85 Fed. Reg. 15,638, 15,638-710 (Mar. 18, 2020). FDA explained that the Rule was meant to "promote greater public understanding of the negative health consequences of cigarette smoking," by focusing on "less-known health consequences of smoking." *Id.* at 15,640.

The Rule replaced seven of the Act's textual warnings with nine new warnings, and adopted eleven graphic images. *Id.* at 15,685, 15,708-09. Together, the textual warnings and graphic images (reproduced in the Appendix) occupy the top 50% of the front and back of cigarette packages and 20% of cigarette advertisements. *Id.* at 15,709; *see id.* at 15,641.

B. FDA's Own Analysis Shows that the Selected Warnings Would Mislead Consumers and Convey Inaccurate Information About Smoking Risks.

Before issuing the Proposed Rule, FDA conducted three qualitative studies consisting of focus groups and individual interviews intended to develop and refine the warnings. Specifically, FDA conducted "16 qualitative focus groups" for the textual warnings, 84 Fed. Reg. at 42,767, and "53 in[-]depth individual interviews" and "20 qualitative focus groups" for the pairings of graphic images and textual warnings, *id.* at 42,770-71. Although FDA claimed these studies supported its warning selections, they actually revealed serious problems with the warnings' accuracy and effectiveness. In particular, these studies demonstrated that the graphic warnings convey misleading, confusing, and factually inaccurate messages about smoking health risks. Doc. 71-5 at 345, 347 (First Qualitative Study Report); Doc. 71-6 at 14, 15, 19 (Second Qualitative Study Report), Doc. 71-7 at 81, 137, 139

(Third Qualitative Study Report). For instance, some study participants thought that the erectile-dysfunction image depicted a "strained relationship," infertility, "[i]nsomnia/sleeplessness," or "stress/depression." Doc. 71-7 at 137, 139 (Third Qualitative Study Report). Public comments also demonstrated that all of the Rule's warnings misleadingly exaggerate smoking risks. *Infra* pp. 15-16.

Participants' reactions to FDA's draft graphic warnings raised serious questions about the clarity and accuracy of the messages conveyed. *See infra* pp. 12-14. But instead of probing these issues, FDA withheld the qualitative study reports on the draft warnings for months, *see infra* pp. 22-24, and declined to undertake similar studies of the final warnings. Instead, FDA sought to brush aside the inconvenient results of the qualitative studies because they were "not nationally representative, and do not yield data that can be generalized," 85 Fed. Reg. at 15,666—even though the "quantitative studies" on which FDA did rely suffered from similar limitations. *See infra* pp. 4-6.

C. FDA's Own Analysis Fails To Show that the Rule Will Meaningfully Affect the Public's Knowledge of Smoking Risks.

1. FDA also commissioned two quantitative studies. The first was designed to determine whether the FDA-created *textual* warnings would promote greater public understanding of smoking risks. 84 Fed. Reg. at 42,767. The study split participants into seventeen groups—one viewed the TCA's nine textual warnings, and sixteen viewed eight of the TCA's warnings and one FDA-created warning. Doc. 71-4 at 184 (First Quantitative Study Report). The study then asked "questions assessing beliefs about the negative health consequences of smoking contained in the warning statements." *Id.* at 186. The second study was designed to determine whether the graphic warnings (including text *and* graphics) would increase understanding of smoking risks. 84 Fed. Reg. at 42,771. The study split participants into seventeen groups—one saw a cigarette package and advertisement with one of the current textual warnings, and sixteen saw a package and advertisement with one of the new graphic warnings. Doc. 71-5 at 13. (Second Quantitative Study Report). The study (1) tested participants' beliefs about smoking risks, (2) showed them the warnings, (3) re-tested their beliefs after one day, and (4) re-tested their beliefs after fourteen days. *Id.* at 15-16.

2. These studies were not peer reviewed before FDA issued the Proposed Rule, which led to

criticism that they "were not credible." 85 Fed. Reg. at 15,661. FDA responded that its studies had been peer reviewed *subsequent* to the Proposed Rule, and it claimed that the reviewers were largely positive, providing only minor suggestions "to improve the clarity of the study reports." *Id.* Contrary to FDA's characterization, the peer reviewers raised serious, substantive concerns about FDA's studies. *See* Doc. 71-25 at 140-201. Indeed, both studies had "significant short-comings" that make them "unreliable." Doc. 71-11 at 237-38 (Klick Report).

First, reviewers noted that both quantitative studies lacked an adequate theoretical framework to support the concepts for which they purported to be testing. *See* Doc. 71-25 at 148 (Peer Review Report) ("looks a little like *post-hoc rationalization"); id.* at 164 ("neither based in empirical evidence nor theory"); *id.* at 148, 155, 174, 180. Reviewers were concerned that FDA did not use "standard" measures, and failed to demonstrate the validity of its novel measures. *Id.* at 153, 156, 160-61; *see also id.* at 150, 168, 184. Reviewers were particularly critical of the "primary outcomes" FDA used to measure understanding—self-reported learning and new information—and noted the lack of "prior research showing the validity and meaningfulness" of those measures. *Id.* at 159; *see id.* at 166. Reviewers also found FDA's decision to differentiate between "primary" and "secondary" outcomes in the first study to be "arbitrary." *Id.* at 155; *see id.* at 181.

Second, reviewers criticized FDA for failing to use representative samples (and instead using "convenience samples" with "significant asymmetries" in the sample demographics). *Id.* at 169-70. Reviewers noted that using a convenience sample "brings with it a host of potential biases and limits to generalizability versus employing a representative sample." *Id.* at 181; *see id.* at 179; *id.* at 185 ("significant weakness"); *id.* at 186 ("quite serious" limitation); *id.* at 189, 169, 175. OMB agreed that, for this reason, the study findings "may not generalize to the broader U.S. population," and granted the first quantitative study only limited approval.[4]

Third, reviewers raised a host of other concerns. For example, reviewers were concerned that

[4] OMB, *Notice of Office of Management and Budget Action, Experimental Study on Warning Statements for Cigarette Graphic Health Warnings*, Ref. No. 201708-0910-011 (Jan. 29, 2018), https://tinyurl.com/ybwk7ptv ("OMB Notice"); *see also infra* pp. 10, 14.

FDA's testing method primed study participants, skewed the results, and tested memory rather than understanding. *See* Doc. 71-25 at 156 (Peer Review Report) (test of participants' "memory and test taking skills" rather than "understanding"); *id.* at 173-74 ("distorts the way people process the information"); *id.* at 201 ("priming effect"). Reviewers also expressed concerns about the conclusions FDA drew from the data because the revised warnings were ranked "lower" on "factualness" than the Surgeon General's warnings. *Id.* at 164; *see id.* at 174. A reviewer also criticized FDA's failure to include the believability criterion in the second study as "problematic," because the poor believability results of the first study had "undermined the legitimacy and utility of the warnings." *Id.*

FDA made minimal effort to address these fundamental flaws, offering no substantive revisions. For example, in response to a suggestion that additional measures be used, FDA said that "Study 1 is complete, and we are unable to include new measures in this study." Doc. 71-26 at 28 (FDA Response to Peer Review Report). FDA likewise did not add measures to its second study and defended its use of novel measures. *Id.* at 36. FDA did not resolve the problems with the studies' samples, or address any other structural defect identified by the reviewers. It just added "clarifying details" and said that nothing "change[d] the results." 85 Fed. Reg. 15,661. Nor did FDA give the public a chance to comment on any of this.

3. Even taken at face value, however, these studies demonstrate that the Rule will not have a material impact on the public's understanding of smoking risks. *First*, these studies show that the public already knows about many of those risks. Specifically, the first quantitative study showed that the "[Act's] warning statements were new information to relatively few participants," Doc. 71-4 at 174 (First Quantitative Study Report), and that participants did not consider eight of the nine FDA-created textual warnings in the final Rule (the "diabetes," "amputation," "cataracts," "bladder cancer," "erectile dysfunction," "head and neck cancer," "heart disease," and "fetal growth" warnings) to be more "informative" than the Act's warnings. *Id.* at 240.

Second, the studies performed dismally when it came to altering participants' beliefs about smoking risks, which is the best measurement of whether the warnings would promote greater public understanding of those risks. The first study showed that, when compared to the Act's textual

warnings, seven of the nine FDA-created textual warnings in the final Rule (the "cataracts," "bladder cancer," "erectile dysfunction," "head and neck cancer," "heart disease," "fetal growth," and "COPD" warnings) did not have a statistically significant effect on the participants' beliefs after appropriate statistical adjustments. Doc. 71-4 at 175, 227, 245-46 (First Quantitative Study Report). And the second quantitative study fared little better. That study showed that five of the Rule's eleven warnings (the "harm your children," "erectile dysfunction," "heart disease," "fetal growth," and "COPD" warnings) did not have a statistically significant effect on participants' beliefs. *See* Doc. 71-5 at 111-113 (Second Quantitative Study Report). In addition, five more warnings had a small effect on the participants' knowledge after one day, but a much smaller effect after fourteen days. *See id.* at 106-07, 110-11 (showing that the alleged increase in knowledge had dropped by 66% for "diabetes," 50% for "head and neck cancer," 50% for "cataracts," 40% for "bladder cancer," and 34% for "amputation").[5] In other words, out of eleven warnings, five had no effect on participants' knowledge, and five more had only a small effect that quickly began to dissipate. This indicates that FDA's purported "health beliefs assessment" was not actually testing participants' understanding or acceptance of the information, and was at most capturing their (dissipating) ability to recall it.

D. Plaintiffs Challenge the Rule.

In April 2020, Plaintiffs challenged the Rule, arguing that it violated the First Amendment, the APA, and the TCA. Doc. 1. This Court granted summary judgment to Plaintiffs on their First Amendment challenge. Doc. 106 at 43. Applying the standard of scrutiny set forth in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), this Court concluded that none of the warnings here are "purely factual" because "each warning" is subject to multiple reasonable interpretations. *Id.* at 28-29. This Court also identified "a broader problem": "FDA has not made a record-based showing" "that each image-and-text pairing conveys only one, unambiguous meaning that is factually correct." *Id.* at 29. This Court went on to hold that "[t]he government has not shown that compelling these large,

[5] The percentage results from comparing the increase in mean health beliefs from Session 1 to Session 2 to the increase from Session 1 to Session 3.

graphic warnings is necessary in light of other options," including public-information campaigns and "smaller or differently placed warnings." *Id.* at 31, 33-34. Having held that the Rule violates the First Amendment, this Court did not reach Plaintiffs' statutory claims. *Id.* at 35. This Court issued a declaratory judgment and vacated the Rule. *Id.*

The Fifth Circuit reversed on the First Amendment claim and remanded the statutory claims. *R J Reynolds*, 96 F.4th 863. It held that the warnings are subject to, and satisfy, the *Zauderer* standard. *Id.* at 875-87. The Fifth Circuit explicitly declined to reach the merits of Plaintiffs' statutory claims, which this Court "never addressed." *Id.* at 887 n.77. The Fifth Circuit explained that it "resolved only the constitutional issue," and declined to consider "alleged flaws in the FDA's studies," because "[w]hether FDA's use of the studies survives APA review is a question" to be considered "separately from our *Zauderer* review." *Id.* at 875, 884-85. As the Fifth Circuit explained: "We generally prefer not to resolve a complicated fact-intensive dispute without the benefit of the district court's reasoning, and the instant case is no exception." *Id.* at 887.[6] The Fifth Circuit therefore remanded for the district court to initially analyze and rule on the statutory claims. *Id.*[7]

Plaintiffs sought en banc review, which was denied. Then, in exchange for Plaintiffs agreeing not to seek a stay of the Fifth Circuit's mandate pending the disposition of a petition for writ of certiorari, FDA agreed to forgo enforcement of the Rule against Plaintiffs during the pendency of the Supreme Court proceedings and for 15 months thereafter. Doc. 115 at 3. Plaintiffs timely filed a certiorari petition on their First Amendment claims on August 19, 2024. In opposing certiorari, FDA urged the Supreme Court to deny review in part because, in FDA's view, Plaintiffs' challenge to the Rule "would be better considered under the rubric of the APA." BIO 17, 26. On November 25, 2024, the Supreme Court denied certiorari. *See* Doc. 117; Doc. 120.

STANDARD OF REVIEW

[6] The Fifth Circuit also "pass[ed] no judgment on [this Court's] declination to sever or on its application of vacatur." *R J Reynolds*, 96 F.4th at 887 n.78.

[7] The Fifth Circuit's reference to the remand of Plaintiffs' "APA claims," *R J Reynolds*, 96 F.4th at 887, encompasses Plaintiffs' claims that the Rule violates the TCA, which were brought under the APA. *See* Doc. 1 ¶ 150 (Complaint).

As this Court has previously ruled in this case, it has the "authority to postpone a rule's effective date" pending judicial review. Order, Doc. 33 at 1 (May 8, 2020) (citing 5 U.S.C. § 705); *see also Affinity Healthcare Servs., Inc. v. Sebelius*, 720 F. Supp. 2d 12, 15 n.4 (D.D.C. 2010). Courts, including this one, evaluate motions to stay or postpone agency action using the same four factors used to assess motions for preliminary injunctive relief. *See Texas v. EPA*, 829 F.3d 405, 435 (5th Cir. 2016) (granting stay under § 705 and applying preliminary injunction factors); Order, Doc. 33 at 1-2. Specifically, courts consider (1) whether plaintiffs are "likely to succeed on the merits" of their claims; (2) whether they "will be irreparably injured absent a stay"; (3) whether issuing a stay will "substantially injure the other parties interested in the proceeding" and (4) "where the public interest lies." *Texas*, 829 F.3d at 424 (quoting *Nken v. Holder*, 556 U.S. 418, 434 (2009)). The Fifth Circuit "has refused to apply" the factors "in a rigid ... [or] mechanical fashion." *Campaign for S. Equal. v. Bryant*, 773 F.3d 55, 57 (5th Cir. 2014) (citation omitted). Where a case presents a "serious legal question" and the balance of equities heavily favors a stay, the petition need only present a substantial case on the merits. *Id.*

ARGUMENT

I. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS.

A. The Rule Violates the Administrative Procedure Act.

1. FDA acted arbitrarily and capriciously.

The APA directs courts to set aside agency action that is "arbitrary [and] capricious." 5 U.S.C. § 706(2)(A). "[T]he agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (quotation marks omitted); *accord Sw. Elec. Power Co. v. EPA*, 920 F.3d 999, 1013 (5th Cir. 2019). This mandate gives rise to at least six subsidiary requirements, each of which FDA violated here, and each of which independently justifies setting aside the Rule.

a. *FDA's explanation for the Rule defied all available evidence.*

An agency acts arbitrarily and capriciously when it "offer[s] an explanation for its decision that

runs counter to the evidence before the agency." *State Farm*, 463 U.S. at 43; *see Rest. L. Ctr. v. Dep't of Lab.*, 120 F.4th 163, 175 (5th Cir. 2024). Agency action also must be supported by substantial evidence. *See R.J. Reynolds*, 696 F.3d at 1218; *Safe Extensions, Inc. v. FAA*, 509 F.3d 593, 604 (D.C. Cir. 2007). Here, the Rule lacks evidence that the warnings will further FDA's only asserted interest: "promot[ing] greater public understanding" of particular smoking risks, 84 Fed. Reg. at 42,755.

FDA conducted just two quantitative studies to support its asserted interest. (Although FDA cites other studies, 85 Fed. Reg. at 15,664, all of them involved different warnings and overwhelmingly discussed their effects on non-U.S. populations.) The two quantitative studies are deeply flawed. First, the studies' participants were "recruited from an Internet panel" and then "screened for inclusion into the study." 82 Fed. Reg. 43,765. As OMB later explained, however, this recruitment method is subject to bias, and FDA's findings "may not generalize to the broader U.S. population." OMB Notice; *see supra* pp. 4-6. The second quantitative study suffered from the same problems. *See* Doc. 71-4 at 253 (Second Quantitative Study Report). These are "significant short-comings" that make FDA's studies "unreliable." Doc. 71-11 at 237-39 (Klick Report).

Even taken at face value, these studies do not support FDA's Rule—they undermine it. The first study showed that, when compared to the Tobacco Control Act's textual warnings, seven of the nine FDA-created warnings did not lead to a statistically significant increase in the participants' beliefs that smoking has the negative health consequences corresponding to that warning. Doc. 71-4 at 245 46 (First Quantitative Study Report). And the second study showed that five of the Rule's eleven graphic warnings had no significant effect on the participants' beliefs about smoking risks, and five more had only a small effect that quickly started wearing off. *See supra* pp. 6-7.

FDA did not do any follow-up testing to determine why the warnings did such a poor job of changing study participants' beliefs. But the evidence before FDA offers several possibilities.

i. For starters, the public already knows the risks of smoking, and the Rule will not materially improve that understanding. For decades, cigarette packages and advertising have displayed warnings that inform the public about smoking risks. *See* Pub. L. No. 89-92, 79 Stat. 282 (1965); Pub. L. No. 98-474, 98 Stat. 2200 (1984). The public has also received such information from other sources,

including the government, public-health entities, doctors, insurers, and schools. *See* Doc. 71-11 at 157 (Reynolds Comments); *id.* at 197-99 (Klick Report); *id.* at 287-93 (Steenkamp Report); *see also United States v. Philip Morris USA Inc.*, No. 99-CV-2496, 2016 WL 3951273, at *1 (D.D.C. Apr. 19, 2016) (requiring tobacco companies to make corrective statements).

As a result, the public already knows that smoking is harmful. Indeed, FDA's own Population Assessment of Tobacco and Health ("PATH") survey, a "nationally representative longitudinal dataset," shows that *99.5% of individuals believe that cigarette smoking is harmful to health*. Doc. 71-11 at 200-06 (Klick Report). The public also knows about the major risks of smoking. For example, PATH data show that 94% of people believe that smoking causes lung disease, and 88% believe that smoking causes heart disease. *Id.* at 212-15; *see id.* at 221. It would be difficult, if not impossible, to improve these numbers. *Id.* at 200.

FDA tries to sidestep this problem by claiming that the warnings address "less-known health consequences of smoking." 84 Fed. Reg. at 42,756-57. This is fundamentally flawed because FDA's evidence shows that six of the Rule's warnings describe *well-known* risks:

- **"Tobacco smoke can harm your children."** FDA concedes[8] this risk is well-known, and its study shows this warning was new information to only 2.6% of adults. *See* Doc. 71-5 at 347, 349 (First Qualitative Study Report); Doc. 71-11 at 217-18 (Klick Report).
- **"Tobacco smoke causes fatal lung disease in nonsmokers."** This is concededly well-known, and FDA's data confirm that 83% of people believe second-hand smoke causes lung disease in non-smokers. Doc. 71-11 at 218 (Klick Report).
- **"Smoking causes head and neck cancer."** FDA has acknowledged evidence that more than 90% of people know smoking causes various head and neck cancers. 84 Fed. Reg. at 42,761 (citing Dannielle E. Kelley et al., *Effective Message Elements for Disclosures About Chemicals in Cigarette Smoke*, 20 Nicotine & Tobacco Research 1047, 1051 (2018)); Doc. 71-11 at 215-16 (Klick Report).
- **"Smoking can cause heart disease and strokes by clogging arteries."** FDA has conceded this is well-known, *see supra* note 8, and FDA's data show that 88% of people understand the heart-disease risk and 80% understand the stroke risk. *See* 84 Fed. Reg.

[8] FDA has acknowledged "the public already has a high pre-existing level of knowledge of the specific health consequences described in the warnings" that were tested in certain studies. 84 Fed. Reg. at 42,764. Because those four studies tested *all* of the Act's warnings, FDA has effectively conceded that each of those risks is well-known. *See also id.* at 42,767 n.5.

at 42,758; Doc. 71-11 at 213 (Klick Report).

- **"Smoking during pregnancy stunts fetal growth."** 86% of people believe smoking causes harm to fetuses (per FDA's PATH data), Doc. 71-11 at 217 (Klick Report), and FDA has relied on evidence that people know about the smoking-related risks of low birth weight and premature birth. 84 Fed. Reg. at 42,761 (citing Denise M. Levis et al., *Women's Perspectives on Smoking and Pregnancy and Graphic Warning Labels*, 38(5) Am. J. of Health Behavior 755 (2014)); *see also* Doc. 71-5 at 347 (First Qualitative Study Report).
- **"Smoking causes COPD, a lung disease that can be fatal."** FDA concedes this is well-known, and FDA's data show that 94% of people believe smoking causes lung disease. 84 Fed. Reg. at 42,756; Doc. 71-11 at 214-15 (Klick Report); *see also* Doc. 71-5 at 334 (First Qualitative Study Report).

ii. In addition, FDA's studies showed that many of the FDA-created textual warnings were not believable. For instance, in FDA's first qualitative study, participants had a "widespread negative reaction" to warnings that said smoking "causes" a disease, rather than "can cause," "may cause," or "increases the risk of." Doc. 71-5 at 321, 366 (First Qualitative Study Report). This was the study's "most prevalent finding." *Id.* at 366; *see also id.* at 329, 331, 333, 340-41, 345, 347-50, 352, 359-60. Participants also "expressed a desire for more information about the relationship between the amount and duration of smoking … to the health effects of smoking." *Id.* at 321; *see also id.* at 352, 366. This was one of the study's "key findings." *Id.* at 320. Relatedly, participants often did not believe warnings about less-intuitive risks—like bladder cancer, diabetes, or erectile dysfunction—without more information about how smoking causes them. *See id.* at 337-38, 359, 367.

FDA's first quantitative study confirmed that the warnings had serious believability problems. Participants thought that six of the warnings (the "diabetes," "amputation," "cataracts," "bladder cancer," "erectile dysfunction," and "head and neck cancer" warnings)—including all of the warnings that addressed less-intuitive risks—were less "believable" than the Act's warnings. Doc. 71-4 at 238.

FDA responded to these poor results by refusing to make any meaningful changes, and even dropped the "believability" question from the second quantitative study. *See* Doc. 71-25 at 168, 175 (Peer Review Report). FDA explained that people's "health beliefs" were "unlikely to change with a single brief exposure to the text-only statements—as was provided in this first quantitative consumer research study." 84 Fed. Reg. at 42,769. Instead of designing a longer-term study, however, FDA moved the goalposts in its second study by switching focus to two different questions: (1) whether

the warning was "new information" to participants, and (2) whether participants reported that they "learned something" from the warning. *See* 84 Fed. Reg. at 42,768, 42,771. But these questions were criticized by reviewers as non-standard measures of questionable validity, *see* Doc. 71-25 at 155, 159, 169, and instead reflect what a peer reviewer called "*post hoc rationalization*," *id.* at 148.

First, the "new information" and "learned something" questions say little—if anything—about whether warnings will improve the public's understanding of smoking risks. As FDA explains, learning is a two-step process: "[T]o understand a message, individuals must first attend to the message (*i.e.*, notice and be made aware of the message), and then they must process the information in the message (*i.e.*, acquire knowledge of and learn that information)." 85 Fed. Reg. at 15,665-66. But FDA's chosen measures do not capture this learning process.

FDA contends that "new information" helps with the *first* step because "people are more likely to pay attention to information that is new." 84 Fed. Reg. at 42,769. But FDA does not explain how "new information" helps with the *second* step: whether people will "acquire knowledge of and learn that information." 85 Fed. Reg. at 15,656. And it is quite easy to see how a warning that contains "new information" might not lead to learning. FDA's own studies provide a compelling example. FDA says that the "erectile dysfunction" warning conveys "new information." *See* Doc. 71-5 at 102 (Second Quantitative Study Report). But FDA's study also shows that this warning was not believable, and neither the textual warning nor the graphic warning led to a statistically significant increase in the number of participants who believed that smoking caused this problem. *See* Doc. 71-4 at 239, 245 (First Quantitative Study Report); Doc. 71-5 at 111. Similarly, *none* of the final graphic warnings "reliably outperform[ed] the current Surgeon General's warnings" on the "perceived factualness" criteria. 85 Fed. Reg. at 15,659. Indeed, most "were perceived as factual statistically significantly less than the Surgeon General's warnings." *Id.* at 15,660. FDA eventually had to admit this fact when it corrected an earlier study report which misleadingly suggested to the contrary. *Compare* Doc. 71-24 at 307 (Revised Second Quantitative Study Report), *with* Doc. 71-5 at 117-18 (Second Quantitative Study Report). In the end, FDA's assertion that "new information" will promote greater public understanding is nothing more than "mere speculation," *R.J. Reynolds*, 696 F.3d at 1219.

Second, even if these questions were relevant, the evidence that FDA developed failed to demonstrate *meaningful* gains in consumers' knowledge of relevant health risks. FDA tested whether the graphic warnings scored better on the "new information" and "self-reported learning" metrics than the current textual warnings did. 84 Fed. Reg. at 42,772. But that is an exceedingly low bar. The current warnings cover diseases like lung cancer, heart disease, and emphysema (a type of COPD) that practically everyone already knows about. *See supra* pp. 6-7, 10-12. And as FDA repeatedly points out, the current warnings "have not changed in more than 35 years" and smokers see them "over 5,100 times per year." 85 Fed. Reg. at 15,653. That a graphic warning conveyed more "new information" than a 35-year-old, universally understood warning is a small achievement indeed.

Third, FDA cannot show that its studies are reliable. Relying on unreliable data is arbitrary and capricious. *See, e.g.*, *City of Stoughton v. EPA*, 858 F.2d 747, 750 (D.C. Cir. 1988) (argument that "the use of invalid data as a basis for administrative action is arbitrary and capricious" "correctly states the law"); *McElmurray v. USDA*, 535 F. Supp. 2d 1318, 1325 (S.D. Ga. 2008) ("[T]he APA demands that agency decisions not be based on unreliable evidence[.]"); *NRDC v. Zinke*, 347 F. Supp. 3d 465, 495 (E.D. Cal. 2018). As explained above, neither of FDA's studies here is nationally representative, which means that their findings "may not generalize to the broader U.S. population." OMB Notice; *see* 85 Fed. Reg. at 15,660. Moreover, the studies are self-contradictory. For example, the first quantitative study concluded that all of the FDA-created textual warnings conveyed more "new information" than the Act's warnings. Doc. 71-4 at 174, 236-37 (First Quantitative Study Report). At the same time, however, eight of the ten FDA-created textual warnings were no more "informative" than the Act's warnings. *Id.* at 240. Both of those things cannot be true. Thus, the Court should give zero weight to the "new information" and "self-reported learning" questions.

iii. Finally, although not designed to target this issue, FDA's own studies demonstrated that consumers would take away misleading and inaccurate messages from the Rule's images and text. For example:

- Some participants interpreted the near-final erectile-dysfunction image as referring to stress, insomnia, or infertility. Doc. 71-7 at 137-39 (Third Qualitative Study Report).

- Some participants stated "that it was unclear what was wrong with the child" in the near-final "Sick Child" image. *Id.* at 81.
- The draft statement that "Smoking Causes Diabetes" inaccurately conveyed to consumers that smoking is the sole or primary cause of diabetes, or invariably causes diabetes. Doc. 71-5 at 359 (First Qualitative Study Report).

Indeed, the reactions of study participants confirm that *every* graphic warning will mislead, confuse, or shock consumers. *See* Doc. 34-4 at 2-9 (collecting illustrative responses from study participants); Doc. 59-2 at 1-25 (same).[9]

It is thus no surprise that this Court found that "each of the graphic warnings" can be reasonably interpreted to convey inaccurate meanings. Doc. 106 at 31. As the Court explained, the "neck-tumor" image is subject to different reasonable interpretations, including that the warning is "an effort to provoke repulsion" by portraying "a stylized, exaggerated representation of neck cancer." *Id.* at 28. The "open-heart surgery" image could be reasonably interpreted as showing "the most common treatment for heart disease," yet FDA presented "no evidence of that assertion's truth"; rather, a different intervention is indisputably "2.5 times more common than open-heart surgery." *Id.* at 29 (citing 85 Fed. Reg. at 15,677-78). Consumers could also interpret that image to mean that "open-heart surgery is the best treatment for heart disease, even if not the most common." *Id.* at 30. But that is unsupported by the record. *Id.* The same goes for the cataracts warning: The warning mentions both cataracts *and* blindness, so a consumer could reasonably interpret it as depicting blindness. *Id.* And even if the "text were limited to cataracts," "some consumers may reasonably interpret the image as depicting the most common result of cataracts," but FDA presented "no evidence of that depiction being accurate." *Id.* Rather, as "commenters told the FDA" and FDA again conceded, "cataracts in the United States are typically treated long before they progress to the stage shown." *Id.*

In addition, *each* of the remaining images is misleading and confusing:

- The "Diseased Non-Smoker's Lungs" image depicts lungs that "do not look like a non-smoker's lungs" and have unusually large and numerous cancerous lesions. Doc.

[9] *See also* Doc. 71-5 at 329, 331, 333, 336, 340-43, 357-60 (First Qualitative Study Report); Doc. 71-6 at 12, 19, 21, 23, 25, 32, 34, 36-39, 41, 60-62, 76-77, 80, 92, 96, 124-25, 127, 129, 142-44, 157-58, 160, 163-64 (Second Qualitative Study Report); Doc. 71-7 at 81, 83, 88, 90, 97, 111-12, 126, 131, 134-35, 137, 139 (Third Qualitative Study Report).

71-12 at 118 (Farber Declaration).

- The "Diseased Feet" image depicts a condition that could affect, at most, one in 1,000 smokers. Doc. 71-12 at 125-26 (Wagmeister Declaration).
- The "Sick Child" image depicts a rare "worst case scenario" of a child being hospitalized, and requiring oxygen, due to a tobacco-smoke-induced asthma attack. Doc. 71-12 at 109-10 (Brooks Declaration).
- The "Crying Baby" image depicts a newborn weighing four pounds, when even the low end of normal birth weight for babies born to smoking women is more than five pounds. Doc. 71-11 at 152-53 (Reynolds Comments).
- The "Bloody Urine" image is misleading because "the association between bladder cancer and consistent smoking of up to ten cigarettes per day was not statistically significant." Doc. 71-21 at 35 (ITG Brands Comments) (citing 84 Fed. Reg. at 42,774).
- The "Erectile Dysfunction" image misleadingly suggests that erectile dysfunction is commonplace for smokers. *Id.* at 37-38.
- The "COPD Nasal Cannula" image misleadingly "depicts a 'worst case scenario,'" in which a smoker not only develops COPD, but requires home oxygen. *Id.* at 37.
- The "Finger Prick" image is "misleading in that it does not convey either the absolute or relative risk of" smoking-related diabetes, and instead suggests that smoking results in diabetes, requiring painful blood-glucose monitoring. *Id.* at 39.

FDA ignored this plentiful record evidence that the warnings are misleading and confusing—and therefore could not accomplish its goal of "promot[ing] greater public understanding" of particular smoking risks. 84 Fed. Reg. at 42,755. By ignoring the studies' flaws and reaching a conclusion counter to the evidence, FDA acted unlawfully.

b. *FDA failed to consider a important aspects of the problem: whether the warnings would reduce smoking.*

All of this is reflective of FDA's more fundamental failure to consider "important aspect[s] of the problem." *State Farm*, 463 U.S. at 43; *see Cigar Ass'n of Am. v. FDA*, 964 F.3d 56, 61 (D.C. Cir. 2020). *First*, FDA ignored whether the Rule would help people quit smoking, which is an important aspect of the analysis. *See, e.g.*, Doc. 71-11 at 186 (Reynolds Comments) (this is a "crucial defect"); Doc. 71-21 at 44-45 (ITG Brands Comments). As the D.C. Circuit observed with respect to FDA's rule requiring far *less* intrusive warnings on cigar and pipe-tobacco packaging and advertising, "[w]hen requiring a product to bear such obtrusive and expensive health warnings, it is difficult to imagine a more important 'aspect of the problem' than whether the warnings will actually affect product usage."

Cigar Ass'n, 964 F.3d at 62 (citation omitted).

It's no surprise that FDA would be reluctant to consider this aspect of the problem. After all, in the original graphic-warnings rulemaking, FDA's own evidence showed that the warnings would have an effect on smoking that was statistically indistinguishable from zero. 76 Fed. Reg. at 36,775-76. This led the D.C. Circuit to hold that "FDA has not provided a shred of evidence … showing that the graphic warnings will 'directly advance' its interest in reducing the number of Americans who smoke." *R.J. Reynolds*, 696 F.3d at 1219. And the evidence in this rulemaking only reinforces that conclusion. Most pointedly, FDA's own survey showed that educating people about the risks described in the Rule will have "zero direct effect on smoking behavior." Doc. 71-11 at 211 (Klick Report). But reluctance to address a difficult subject does not relieve an agency of its obligation to address all important aspects of the problem before it.

Second, FDA failed to consider the emotional impact of the warnings. This is an important aspect of the problem when mandating shocking and provocative warnings such as these. As the Court previously concluded in this case (when ruling on the First Amendment claim), "[t]he imagery in the warnings here is provocative." Doc. 106 at 28. Similar reactions dominated coverage of the Rule in the press. *See* Doc. 34 at 34. And in FDA's own study, respondents volunteered that the warnings elicited emotional reactions.[10] Yet FDA concededly ignored this issue and made no effort to assess the emotional impact of the warnings. *See* 85 Fed. Reg. at 15,668 ("an assessment of emotional responses or behavioral study outcomes is not aligned with the final rule").

c. *FDA ignored several obvious less-burdensome alternatives to provocative graphic warnings.*

FDA also ignored several less-burdensome alternatives to provocative graphic warnings. Agency action is arbitrary and capricious if an agency ignores an alternative approach that is "neither frivolous nor out of bounds." *Chamber of Com. v. SEC*, 412 F.3d 133, 144-45 (D.C. Cir. 2005); *accord*

[10] Doc. 71-6 at 23, 36, 61, 96; Doc. 71-7 at 13, 17, 25, 29 (Second Qualitative Study Report) ("grotesque," "gruesome," "disgusting," "heartbreaking," "startling," "powerfully disturbing," "scary," "terrifying," "send[] me into despair," "really creep me out," "really just disgust[] me," had "shock value," depicted "worst nightmare"); *see also* Doc. 59-2 (cataloging similar consumer reactions).

Rest. L. Ctr., 120 F.4th at 176 (holding agency action arbitrary where, among other things, "there were other options for [the agency] to consider").

Despite the significant burdens imposed by the Rule, FDA failed to consider alternative approaches here, including several less-burdensome alternatives proposed by Reynolds that would, to an equal or greater extent than the Rule, advance FDA's stated goal of "promot[ing] greater public understanding" of specific smoking risks, 84 Fed. Reg. at 42,755. These include: less provocative warnings; non-misleading warnings; text-only warnings; smaller, differently placed warnings; or a public-information campaign. *See* Doc. 71-11 at 175 (Reynolds Comments). FDA's Rule did not consider any of these alternatives, much less explain why it rejected them. Indeed, as this Court previously recognized, "the government has not shown that compelling these large, graphic warnings is necessary in light of other options." Doc. 106 at 33.

Most obviously, the government could find alternative ways of delivering the information—such as by increasing its own anti-smoking messaging (or funding for anti-smoking programs and advertising by third parties). *Id.* at 33-34. As this Court has already recognized, a public-information campaign "offers the ability to target particular groups in different channels of communication with different messages." *Id.* at 33. Moreover, FDA has touted these public-information campaigns as "highly successful in educating youth about the dangers of smoking." *Id.*; *see* Doc. 71-11 at 176-77 (Reynolds Comments); *id.* at 289-93 (Steenkamp Report). And yet, it is undisputed that FDA has never even once run a campaign addressing any of the risks addressed in the warnings.

This Court was also correct that FDA failed to consider the potential efficacy of less-burdensome warnings. Doc. 106 at 34. For instance, FDA could change the warnings' text, location, and/or size. But FDA never even considered these options and instead relied on generic conclusions that bigger is better—an approach that would equally justify warnings that take up 90% of packaging. Another alternative that FDA should have considered is textual warnings without graphic images. *See* Doc. 71-11 at 175-76 (Reynolds Comments); Doc. 71-12 at 12-15 (Iyengar Report). Indeed, in 2018, Reynolds urged FDA to test several less-restrictive alternatives to see whether they would be as

effective as graphic warnings.[11] But FDA flatly refused to test any alternatives, and *disclaimed* any need to consider alternatives not contemplated by the TCA. 85 Fed. Reg. at 15,650 (asserting that testing any alternative not contemplated by the TCA "would not have been an optimal use" of resources).

The record reflects that several of these readily available less-restrictive alternatives would likely have been effective. Doc. 71-11 at 175-76 (Reynolds Comments), *id.* at 192-238 (Klick Report); Doc. 71-12 at 12-15 (Iyengar Report); Doc. 71-14 at 14 (Altria Comments). For instance, textual warnings have worked before, helping to maintain the effectively universal knowledge about smoking risks like lung cancer, heart disease, and emphysema, *see supra* pp. 6-7, 10-12, and FDA does not explain why they would not work again. In addition, an expert study compared FDA's warnings to several less-restrictive alternatives and found very few statistically significant differences regarding the amount of new information conveyed and respondents' beliefs about smoking risks after viewing the warnings. Doc. 71-12 at 12-15 (Iyengar Report). For example, for the "new information" question, there were no statistically significant differences between FDA's warnings and text-only warnings on the side of the pack. *Id.* at 12. Likewise, for knowledge of smoking risks, there were no statistically significant differences between FDA's warnings and text-and-graphics warnings on the side of the pack. *Id.* at 13. Other studies on less-restrictive alternatives have reached similar conclusions. Doc. 71-11 at 236 (Klick Report); *id.* at 175-76 (Reynolds Comments) (citing studies); Doc. 71-14 at 14 (Altria Comments) (same). But FDA failed to consider *any* of these alternatives.

FDA may argue that some of these alternatives were unavailable to it because they are not permitted by the TCA. But as Plaintiffs have repeatedly explained—and FDA has never contested—FDA's overly broad understanding of its power to change "label requirements" implies that FDA is also free to change the warnings' size and placement. Doc. 37 at 75; Gov't COA Brief at 37. Thus, under FDA's *own view* as expressed in litigation, it would have been free to consider smaller or

[11] For example, Reynolds suggested that FDA "show one group of participants a package with the current [textual] warnings, show 16 groups a package with the new textual warnings, and show 16 more groups a package with the new textual warnings and graphic images." *See* Doc. 71-11 at 176 (Reynolds Comments). This type of study would have "allow[ed] FDA to determine how much the graphic images contribute, if at all, to FDA's stated goal" of conveying information to the public. *Id.*

differently placed warnings. FDA therefore has no excuse for failing to at least consider those options (so it could, at a minimum, explain why they were unavailable).

Moreover, FDA's argument cannot be squared with its own approach to considering alternatives. FDA considered alternative versions of the Rule that would have taken effect after 6 months or 24 months. *See, e.g.*, Doc. 71-5 at 284-92 (Cost-Benefit Analysis). But the TCA expressly requires that the Rule include an effective date of 15 months. Pub L. No. 111-31, 123 Stat. 1776, 1845 § 201(b) (2009). Thus, FDA clearly thought it was appropriate and worthwhile to consider alternatives that are not contemplated by the TCA, and it therefore cannot use the TCA as an excuse for failing to consider the alternatives proposed by Reynolds.[12]

d. ***FDA's analysis was entirely inadequate even for the few minor alternatives it did consider.***

FDA considered only three alternative approaches—the two alternative effective dates mentioned above, and a version of the Rule that would require only nine warnings. Doc. 71-5 at 284-95 (Cost-Benefit Analysis). But even as to those alternatives, FDA provided no rational explanation for rejecting them. For example, as to the nine-warnings option, FDA found (unsurprisingly) that it would be less costly than the Rule, which requires more warnings. *Id.* at 292-95. Yet FDA offered no explanation for why it chose not to adopt this or any other alternative. This complete failure of explanation is no accident or oversight: As explained below, FDA *cannot* demonstrate that the greater cost of its chosen approach is justified because it has *never quantified* the Rule's purported benefits. FDA's total failure to justify why it selected its approach instead of the alternatives violates the APA.

e. ***FDA failed to engage in a proper cost-benefit analysis.***

"[W]hen an agency decides to rely on a cost-benefit analysis as part of its rulemaking, a serious flaw undermining that analysis can render the rule unreasonable." *Idaho Conservation League v. Wheeler*,

[12] *See Sw. Elec. Power*, 920 F.3d at 1030 (regulation "cannot stand" where the "agency's rationales contradict themselves"); *Chamber of Com. v. U.S. Dep't of Labor*, 885 F.3d 360, 382 (5th Cir. 2018) ("Illogic and internal inconsistency are characteristic of arbitrary and unreasonable agency action."); *ANR Storage Co. v. FERC*, 904 F.3d 1020, 1028 (D.C. Cir. 2018) ("Because [the agency's] decision is internally inconsistent, it is arbitrary and capricious.").

930 F.3d 494, 507 (D.C. Cir. 2019) (quotation marks omitted). In particular, "the agency must identify benefits that bear a rational relationship … to the costs imposed." *Chamber of Com. v. SEC*, 85 F.4th 760, 777 (5th Cir. 2023) (quotation marks omitted). Here, FDA's cost-benefit "analysis" includes a fatal flaw: a complete failure to quantify the Rule's benefits. In fact, FDA expressly disclaimed any attempt to quantify benefits. FDA said that "there is a high level of uncertainty around quantitative economic benefits" and thus chose to "describe them qualitatively." Doc. 71-5 at 243 (Cost-Benefit Analysis). Thus, FDA claimed it could not "compare benefits and costs directly." *Id.* at 249.

Instead of attempting to quantify the Rule's benefits, FDA relied on a "break-even calculation." It estimated the Rule would cost about $1.6 billion, 84 Fed. Reg. at 42,756; 85 Fed. Reg. at 15,698, and then concluded that the Rule would be a net benefit if the value of the warning on each cigarette package was "about $0.01." Doc. 71-5 at 278-79 (Cost-Benefit Analysis); *see* Doc. 71-24 at 438 (Final Regulatory Analysis). But FDA provided *no reason* to believe that the informational benefit is worth $0.01 or more per pack. FDA's choice to describe the benefits qualitatively leaves it unable to explain why the Rule's (more costly) approach is better than the alternatives. That is textbook failure to articulate a satisfactory explanation for its action, and is arbitrary.[13]

f. *FDA did not respond meaningfully to comments.*

Finally, a rule is arbitrary and capricious if the agency fails "'to respond meaningfully' to objections raised by a party." *PPL Wallingford Energy LLC v. FERC*, 419 F.3d 1194, 1198 (D.C. Cir. 2005) (citation omitted); *see Ohio v. EPA*, 144 S. Ct. 2040, 2054 (2024); *Chamber of Com*, 85 F.4th at 774. FDA failed this test here. Commenters and reviewers raised significant criticisms of the Proposed Rule and many of the studies therein. *Supra* pp. 4-6. Yet FDA ignored these critiques.

Most prominently, FDA provided *no* meaningful response to criticisms based on its qualitative studies. As noted, FDA's own qualitative studies showed that study participants took away a host of

[13] *See Chamber of Com.*, 85 F.4th at 777 (regulation arbitrary where agency failed to adequately substantiate benefits and costs); *Michigan v. EPA*, 576 U.S. 743, 753 (2015); *Mexican Gulf Fishing Co. v. U.S. Dep't of Com.*, 60 F.4th 956, 966 (5th Cir. 2023) (regulation invalid where "uncontroverted record shows that [it] gives no meaningful benefit"); *Sw. Elec. Power*, 920 F.3d at 1019.

misleading and inaccurate messages from the Rule's images and text. *Supra* pp. 3-4, 14-16. FDA's only response to the criticism that it ignored the results of its own qualitative studies was that those studies "d[id] not yield data that can be generalized." 85 Fed. Reg. at 15,666-67. But FDA cannot say these studies should be ignored altogether, because the agency itself "used" those studies "to inform further research and development," *id.* at 15,667. Thus, FDA has to explain why it ignored some results and not others. In addition, FDA has no answer to criticisms of *how* it used the studies—in particular, why it chose to "ma[k]e the images more gruesome" after learning the proposed warnings "would evoke negative emotions and thereby convey an ideological, anti-smoking message." *See* Doc. 71-21 at 51 (Reynolds Supplemental Comments).

FDA also ignored criticisms from its own peer reviewers. As noted, the reviewers identified fundamental weaknesses with FDA's studies. *See supra* pp. 4-6. Yet FDA did not address these weaknesses. Instead, it claimed that it performed "an in-depth review of the scientific literature" to select its novel measures—despite the peer reviewers' criticism on that very point—and claimed that making cosmetic, non-substantive changes to its studies was sufficient. *See* 85 Fed. Reg. at 15,661-62. And FDA deepened the error by never allowing anyone to see or comment on the peer review report (or FDA's handling of it)—which is itself an APA violation (as described more fully below).

In short, FDA's self-serving assertions that it developed the graphic warnings through a "science-based, iterative research process," *e.g.*, 84 Fed. Reg. at 42,755; 85 Fed. Reg. at 15,639, ring hollow. To the contrary, FDA barreled toward a pre-ordained conclusion from the beginning without any regard for the evidence, and can now offer only a "post-hoc rationalization" for that outcome. *See* Doc. 71-25 at 148 (Peer Review Report). That is quintessentially arbitrary.

2. FDA failed to provide meaningful notice.

FDA also violated the APA by withholding important information from the public. The APA requires that agencies publish a notice of proposed rulemaking that includes "a description of the subjects and issues involved" in the proposed rule. 5 U.S.C. § 553(b)(3). That notice must contain "sufficient factual detail and rationale for the rule to permit interested parties to comment

meaningfully." *Nat'l Lifeline Ass'n v. FCC*, 921 F.3d 1102, 1115 (D.C. Cir. 2019); *see Phillips Petroleum Co. v. Johnson*, 22 F.3d 616, 620 (5th Cir. 1994), *modified on other grounds,* No. 93-1377, 1994 WL 484506 (5th Cir. Sept. 7, 1994). This includes "technical studies and data that [the agency] has employed." *N. Am.'s Bldg. Trades Unions v. OSHA*, 878 F.3d 271, 301 (D.C. Cir. 2017) (per curiam) (cleaned up); *accord Kern Cnty. Farm Bureau v. Allen*, 450 F.3d 1072, 1076 (9th Cir. 2006).

Here, FDA concealed vital information when it issued the Proposed Rule. The Proposed Rule relied on three qualitative studies and two quantitative studies. *See* 84 Fed. Reg. at 42,765-72, 42,777-78. But when it issued the Proposed Rule, FDA did not release the underlying data for the qualitative studies. Instead, FDA initially released only short descriptions of the studies (it then belatedly released study reports, but did not provide sufficient time for comment on them, *see infra* p. 24). 84 Fed. Reg. at 42,767, 42,771. FDA also hid important information from the public when it provided no notice of—or opportunity to comment on—the peer review reports relating to the two quantitative reports. 85 Fed. Reg. 15,658. That is a remarkable omission given that FDA had implicitly recognized that peer review was *necessary*, by noting that its non-peer-reviewed studies did not represent an agency determination. *See* Doc. 71-4 at 216 (First Quantitative Study Report), 312 (Second Quantitative Study Report). By denying the public the opportunity to comment on the peer review reports, FDA denied the public the opportunity to address a fundamental pillar of FDA's analysis. FDA's failure to release these reports and data violates the "obvious proposition that studies upon which an agency relies in promulgating a rule must be made available during the rulemaking." *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 237 (D.C. Cir. 2008).

Additionally, FDA did not release the final data sets from the quantitative studies, which would have allowed Plaintiffs to examine the data quality and replicate FDA's statistical analyses. Commenters promptly requested this information, but FDA failed to produce it before the comment period closed. *See, e.g.*, Doc. 71-11 at 131-33 (Letter from Altria Client Services); *id.* at 135-37 (Letter from Reynolds's counsel).

In a "Memo to File" that appears in the administrative record, FDA candidly explained why it did not disclose the data. It expressed concern that doing so would "allow third party attempts to

analyze the data in different and potentially selective, biased or misleading ways other than what FDA pre-specified in the statistical analysis plan." Doc. 59-3 at 11 (Administrative Record Excerpts). But as this Court suggested at oral argument in reference to this specific document, "one of the core purposes of notice and comment procedure" is that the agency's pre-conceived analytical methods ought to be subject to comments and critiques. Doc. 85 at 99-100 (12/11/2020 Hearing Transcript). Distrust of the public is no reason to bypass that statutorily required mechanism.

3. FDA failed to provide a meaningful opportunity to comment.

FDA failed to provide sufficient time to comment on the qualitative study reports. The opportunity to comment must be "meaningful," *Nat'l Lifeline*, 921 F.3d at 1115-17, and must include the chance to comment on the agency's evidence, *Owner-Operator Indep. Drivers Ass'n v. Fed. Motor Carrier Safety Admin.*, 494 F.3d 188, 201 (D.C. Cir. 2007); *see Phillips Petroleum*, 22 F.3d at 620; 5 U.S.C. § 553(c). The failure to "reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary" is a "serious procedural error." *Solite Corp. v. EPA*, 952 F.2d 473, 484 (D.C. Cir. 1991) (per curiam) (cleaned up); *accord Kern*, 450 F.3d at 1076.

FDA failed to release the qualitative study reports during the comment period, despite FDA's reliance on them. *See supra* pp. 22-23. Nearly a month after the comment period closed, however, FDA finally placed them in the docket. *See* 84 Fed. Reg. at 60,966-68. FDA then gave the public just fifteen days to comment. *Id.* That too violated the APA. Courts have made clear that a fifteen-day comment period is inadequate. *See, e.g.*, *Nat'l Lifeline*, 921 F.3d at 1117 (2 weeks); *Prometheus Radio Project v. FCC*, 652 F.3d 431, 453 (3d Cir. 2011) (28 days); *N.C. Growers' Ass'n v. UFW*, 702 F.3d 755, 770 (4th Cir. 2012) (10 days). Indeed, the Administrative Conference of the United States has said that sixty days is a "reasonable *minimum* time for comment." *Petry v. Block*, 737 F.2d 1193, 1201 (D.C. Cir. 1984). The paltry comment period here deprived the public of the ability to comment meaningfully.

4. These errors were prejudicial.

The APA directs courts to determine whether an agency error was prejudicial to a party challenging an agency action. *See* 5 U.S.C. § 706. The APA's "reference to prejudicial error is intended

to sum up in succinct fashion the 'harmless error' rule applied by the courts in the review of lower court decisions as well as of administrative bodies." *Shinseki v. Sanders*, 556 U.S. 396, 406 (2009) (cleaned up). But "APA errors are only harmless where the agency would be required to take the same action no matter what. In all other cases, an agency cannot avoid remand." *Wages & White Lion Invs., L.L.C. v. FDA*, 90 F.4th 357, 390 (5th Cir.), *cert. granted*, 144 S. Ct. 2714 (2024). In other words, if a statute *requires* the agency "to reach the result it did," then errors might be harmless if they do not prejudice private parties. *Id.* But the TCA did not require FDA to issue the specific graphic-warnings rule that it did. A showing of harm is therefore not required.

Even if a separate showing of harm is required, the test is not a demanding one. An error is harmless only if it "clearly had no bearing on the procedure used or the substance of [the] decision reached." *Sierra Club v. U.S. Fish & Wildlife Serv.*, 245 F.3d 434, 444 (5th Cir. 2001) (citation omitted); *see Owner-Operator*, 494 F.3d at 202-03; *Texas v. EPA*, 389 F. Supp. 3d 497, 506 (S.D. Tex. 2019). Here, all the notice-and-comment errors clearly *do* bear on the substance or procedure of FDA's decision.[14]

If the qualitative study reports had been released with the Proposed Rule, or if FDA had reopened the comment period for sixty days, Reynolds's experts could have used the reports to deepen their analysis of whether the proposed warnings were misleading or provoked negative emotions, and Reynolds's survey expert could have included additional survey questions based on what those reports revealed regarding what participants found confusing and misleading about the proposed warnings. *See, e.g.*, Doc. 71-12 at 14-15 (Iyengar Report), 110-11 (Brooks Declaration), 113-15 (Davidorf Declaration), 118 (Farber Declaration), 122 (Jones Declaration), 125 (Wagmeister Declaration).

More generally, Plaintiffs could have used the qualitative studies to reinforce their argument in the rulemaking that the warnings were misleading and provoked negative emotions. *See supra* pp. 3-4, 14-16. In this litigation, Plaintiffs identified—and collated in an appendix—significant evidence from the qualitative studies that reinforces their position. *See* Doc. 34 at 39 (relying on Doc. 34-4). Plaintiffs could and would have used all of this information in their comment as well. Plaintiffs have

[14] FDA has never contested the arbitrary-and-capricious errors are prejudicial—and rightly so, as each affects the substantive decisions and/or procedure used. *See Sierra Club*, 245 F.3d at 444.

thoroughly demonstrated how they could have mounted an even more "credible challenge" based on the qualitative studies. *See Owner-Operator*, 494 F.3d at 202-03; *Texas*, 389 F. Supp. 3d at 506.

Plaintiffs were similarly harmed by the failure to timely release the peer review report. As explained above, the peer review report identifies a number of fundamental problems with the studies. *See supra* pp. 4-6. Plaintiffs and their experts could then have explained that these criticisms, coming from FDA's own peer reviewers, severely undercut FDA's rationale for the Rule.

Plaintiffs also suffered prejudice from FDA's failure to timely release the underlying data for all studies. *See supra* pp. 22-24. That data provides evidence that the warnings are confusing, misleading, and designed to provoke negative emotions. *See* Doc. 59-2 at 1-25 (Plaintiffs' Second Appendix). If Plaintiffs had received the data in time, it would have been useful in assessing issues that FDA has failed to adequately explain, such as why it chose to create warnings for some diseases while ignoring other diseases that are more serious and more common, or why it discarded two of the TCA's warnings (about quitting and death), despite reporting *no* data for those two warnings in the first quantitative study. *See* 85 Fed. Reg. at 15,658. In short, Plaintiffs could have mounted an even more "credible challenge" to the Rule if FDA had complied with the APA. *See Owner-Operator*, 494 F.3d at 202-03.

B. The Rule Violates the Tobacco Control Act.

Agencies can only act "within the bounds" of statutes. *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 321 (2014) (citation omitted). The Rule violates the TCA in two different ways. *First*, the Rule increases the total number of graphic warnings from nine to eleven. *Second*, the Rule deletes seven of the Act's textual warnings, and adds nine FDA-created warnings. FDA lacks authority to do either.

1. FDA violated the TCA by increasing the total number of warnings.

FDA violated the Act by changing the total number of warnings from nine to eleven. Section 202(b) empowers FDA to "adjust the format, type size, color graphics, and text" of the warnings. 15 U.S.C. § 1333(d)[2]. Nothing in the TCA (which amended, inter alia, the Food, Drug and Cosmetic Act (FDCA)) however, allows FDA to create *additional* warnings. If Congress had intended to do that, it would have done so expressly, as it has done elsewhere in the FDCA. *See* 21 U.S.C. § 343(q)(2)(A).

In this litigation, FDA has offered two counterarguments. *First*, it has asserted that it has authority to change "any of the label requirements"—including, apparently, in ways not specified by the statutory text. Doc. 67 at 34. As explained above, this eviscerates FDA's separate argument that it did not need to test alternatives not contemplated by the TCA. *See supra* pp. 19-20. On its own terms, though, this argument is unpersuasive. After all, FDA does not have untrammeled authority to alter *anything* related to the label requirements—instead, it has the statutorily specified authority to "adjust the *format, type size, color graphics, and text*" of the label requirements. 15 U.S.C. § 1333(d)[2] (emphasis added). The *number* of warnings is conspicuously absent from that list. And Congress cannot delegate the power to rewrite statutory text. *See, e.g.*, *Clinton v. City of New York*, 524 U.S. 417, 439-40 (1998). Notably, if FDA were right, it would not be limited to eleven warnings—it could dictate as many warnings as it wished.

Second, FDA has raised a bank-shot argument relying on 15 U.S.C. § 1334(a), a preemption provision that does not grant FDA any additional authority but which mentions "additional or different" statements that FDA may require "on any cigarette package by a regulation." This supposedly proves Congress intended to allow FDA to increase the number of graphic warning statements. But as Plaintiffs have repeatedly explained and FDA has never contested, the language in 15 U.S.C. § 1334(a) is best read as referring to other disclosures that FDA can require, such as the smoke-constituent disclosures authorized by 15 U.S.C. § 1333(e).

2. FDA violated the TCA by deleting seven of the Act's textual warnings and adding nine of its own.

FDA also violated the TCA by deleting seven of the Act's textual warnings and adding nine of its own. Section 201(a) says that FDA must "issue regulations that require color graphics depicting the negative health consequences of smoking *to accompany* the label statements specified in subsection (a)(1)." 15 U.S.C. § 1333(d)[1] (emphasis added). This section allows FDA to make only minor typographical adjustments to the warnings' text "so that" they "are clear, conspicuous, legible and appear within the specified area," not to change the language of the statements. *Id.* And Section 202(b)'s putatively broader grant of power to modify the statements kicks in only *after* FDA issues the

graphic-warnings rule required by Section 201(a), as demonstrated by the fact that Section 202(b) empowers FDA to adjust the warnings' "color graphics"—which of course would be impossible before a graphic-warnings rule is promulgated. *Id.* § 1333(d)[2].

II. PLAINTIFFS WILL SUFFER IRREPARABLE HARM ABSENT A STAY.

"Irreparable harm is '[p]erhaps the single most important prerequisite for the issuance'" of temporary relief. *Amegy Bank Nat'l Ass'n v. Monarch Flight II, LLC*, No. 11-cv-3218, 2011 WL 6091807, at *6 (S.D. Tex. Dec. 7, 2011) (quoting 11A WRIGHT & MILLER § 2948). As this Court has already recognized, Plaintiffs will suffer irreparable harm in the absence of a stay.[15]

The Court's earlier analysis holds true today. Indeed, this Court's earlier rulings have already addressed the legal issues governing the necessary showing of irreparable harm, and those earlier rulings are law of the case and "should continue to govern" going forward. *Matter of AKD Invs.*, 79 F.4th 487, 491 (5th Cir. 2023). Nonrecoverable costs are irreparable harm. *See, e.g.*, *Ala. Ass'n of Realtors v. HHS*, 594 U.S. 758, 765 (2021); *Rest. L. Ctr. v. Dep't of Lab.*, 66 F.4th 593, 597 (5th Cir. 2023); *see Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 220-21 (1994) (Scalia, J., concurring in part and concurring in the judgment); *R.J. Reynolds Tobacco Co. v. FDA*, 823 F. Supp. 2d 36, 50 (D.D.C. 2011). "Alleged compliance costs need only be more than de minimis" to constitute irreparable harm. *Career Colleges & Schools of Tex. v. Dep't of Educ.*, 98 F. 4th 220, 236 (5th Cir. 2024) (quotation marks omitted). And it does not matter whether expenditures occur far in advance of a rule's compliance date. *See, e.g.*, *Texas*, 829 F.3d at 416 (irreparable injury where plaintiffs spent money to comply with agency deadlines that were years away). Under this framework, Plaintiffs will clearly suffer irreparable harm absent a stay.

First, Plaintiffs will incur massive costs. The Manufacturer Plaintiffs cannot implement the Rule's requirements without extensive advance preparation and expenditures. Congress and FDA have both recognized as much by providing a 15-month implementation period, *see* Pub. L. No. 111-31,

[15] *See, e.g.*, Doc. 33 (May 8, 2020) ("[R]epresentations in the parties' motion establish irreparable injury absent postponement of the rule's effective date."); *see also* Doc. 80 (Dec. 2, 2020) (postponing effective date for the "equitable reasons given in plaintiffs' motion"); Doc. 89 (Mar. 2, 2021); Doc. 91 (May 21, 2021); Doc. 92 (Aug. 18, 2021); Doc. 93 (Nov. 12, 2021); Doc. 94 (Feb. 10, 2022).

§ 201(b); 85 Fed. Reg. at 15,694; *see also* Doc. 71-5 at 265 (Cost-Benefit Analysis) ("a labeling change requires a minimum of 15 months to fully implement"). FDA has further recognized as much by agreeing to provide Plaintiffs a 15-month implementation period after the conclusion of Supreme Court proceedings. *See* Doc. 114 at 2-3; Doc. 115 at 3.[16] In order for the Manufacturer Plaintiffs to comply with the Rule by February 25, 2026—the end of this 15-month period—they will be forced to almost immediately begin spending millions of dollars and thousands of employee-hours to comply with a regulation despite the substantial chance that it is unlawful. Petitt Decl. ¶¶ 10-15; Sgambelluri Decl. ¶¶ 10-16; Jackson Decl. ¶¶ 8-26. The cost of preparing to comply with the Rule will therefore cause Plaintiffs direct economic harm to the tune of tens of millions of dollars.

Second, as this Court has already recognized, Plaintiffs will not be able to recoup these costs if (as is likely) this Court ultimately holds the Rule unlawful. *See, e.g.*, Doc. 33 at 2; *see also R.J. Reynolds,* 823 F. Supp. 2d at 50 (finding "irreparable economic injury" in the case challenging the 2011 Rule).

III. THE PUBLIC INTEREST AND BALANCE OF EQUITIES FAVOR RELIEF.

Balancing the irreparable harm facing Plaintiffs against the public interest and any harm to the government weighs heavily in favor of a stay. *See Nken*, 556 U.S. at 435; *see also Texas v. United States*, 809 F.3d 134, 187 & n.204 (5th Cir. 2015).

Preserving the status quo costs FDA nothing. While Plaintiffs will incur tens or perhaps hundreds of millions of dollars in unrecoverable costs if a stay is not granted, FDA cannot show any meaningful harm to itself or to the public from a stay. Rather, "[t]he public interest is served when administrative agencies comply with their obligations under the APA." *Clarke v. CFTC*, 74 F.4th 627, 643-44 (5th Cir. 2023); *see Airlines for Am. v. Dep't of Transp*. 110 F.4th 672, 677 (5th Cir. 2024); *Texas v. United States*, 40 F.4th 205, 229 (5th Cir. 2022).

[16] Reinforcing this understanding, FDA issued an industry-wide guidance that established a 15-month compliance runway for manufacturers, noting that "entities may need time to implement the rule's requirements" and "these time periods are consistent with section 201(b) of the Tobacco Control Act and the effective date of the final rule upon its publication." FDA, *Enforcement Policy for Required Warnings for Cigarette Packages and Advertisements* at 3 (Sept. 2024), https://tinyurl.com/p6k596pt; *Enforcement Policy for Required Warnings for Cigarette Packages and Advertisements; Guidance for Industry; Availability*, 89 Fed. Reg. 74,831 (Sept. 13, 2024).

Even if the Court ultimately were to uphold the Rule, the limited delay would not harm the public interest. *First*, FDA has shown no urgency in issuing the Rule, waiting more than seven years after the D.C. Circuit invalidated its first attempt. *See supra* p. 3. If anything, as noted above, the government's recent litigation conduct reinforces its lack of urgency. For starters, to avoid litigating Plaintiffs' motion to stay the Fifth Circuit's mandate, the government agreed not to enforce the Rule against the Plaintiffs—including the Manufacturer Plaintiffs, who collectively account for a significant percentage of the domestic cigarette market—during the pendency of the Supreme Court proceedings and 15 months thereafter. As one perfunctory nod toward urgency, the government insisted that, to get the benefit of the agreement, Plaintiffs would have to file their petition for certiorari on the standard schedule, without seeking an extension. Doc. 114 at 2-3. But after Plaintiffs did so, the government itself sought and received an extension for its opposition. All of this further demonstrates that the public will not suffer any irreparable harm during the pendency of this litigation. *Second*, a short delay would not cause any cigarettes to be sold without adequate warnings that already reflect the major risks of smoking, including lung cancer and heart disease. *See* 15 U.S.C. § 1333 (2008).

Finally, FDA effectively concedes an inability to quantify whether the Rule will meaningfully change smoking behavior or beliefs, and its own studies show that the warnings would not have a meaningful effect on the public's beliefs. *See supra* pp. 4-7, 9-17. Because the Rule would not prevent any material harm to the government's or the public's interests even if implemented permanently, a short delay in its implementation will not meaningfully affect those interests either.[17]

CONCLUSION

Plaintiffs respectfully ask this Court to postpone the Rule's effective date until 15 months after the entry of Final Judgment from this Court on Plaintiffs' claims, and to grant an administrative stay postponing the Rule's effective date until 15 months after the Court rules on this motion.

[17] If this Court grants a stay, Plaintiffs request that it also stay the obligation to comply with related requirements in 21 U.S.C. §§ 387c(a)(2) and 387t(a), as it did when granting and extending previous stays. *See, e.g.*, Extension Order, Doc. 104 (Nov. 7, 2012); Doc. 106 at 4-5.

Respectfully submitted,

December 9, 2024

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CERTIFICATE OF SERVICE

I hereby certify that on December 9, 2024, a true and correct copy of the foregoing was electronically filed with the clerk of court for the U.S. District Court for the Eastern District of Texas, using the CM/ECF system, which will send a notice of electronic filing to all counsel of record.

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CERTIFICATE OF CONFERENCE

I hereby certify, pursuant to Local Rule CV-7(i), that (1) I complied with the meet and confer requirement in Local Rule CV-7(h), and (2) this motion is opposed.

I have conducted the personal conference required by Local Rule CV-7(i). Specifically, on October 28, 2024, I, along with Christian Vergonis, had a telephone conference with Stephen Pezzi (U.S. Department of Justice) to discuss Plaintiffs' Motion. After a collegial discussion where both sides discussed the issues in good faith, and after the parties then exchanged additional emails discussing this motion, counsel for the government asked Plaintiffs to report the government's position as follows:

> Defendants oppose Plaintiffs' motion. The effective date of the Rule was already delayed for several years, despite both Congress's and the FDA's intent that these warnings take effect long ago. The Rule is in effect, and any time-sensitivity now is a direct result of Plaintiffs' request for a significant abeyance of further district-court litigation. *See* ECF Nos. 114-16. In any event, the Fifth Circuit has now unanimously rejected Plaintiffs' primary merits argument, and the Supreme Court denied certiorari without any noted dissent. Under these circumstances, Defendants respectfully reserve their right to seek appellate relief should the Court issue any stay or additional injunctive relief during the remaining pendency of this litigation. *Cf.* Defs.' Notice (Aug. 31, 2022), ECF No. 101. Defendants intend to file an opposition brief during the default timing provided for in the Local Rules, and respectfully request that the Court not act on Plaintiffs' motion until Defendants file their brief.

The conference participants then had two additional telephone conferences on December 6, 2024, where they concluded that the discussion had ended in an impasse, leaving an open issue for the Court to resolve.

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